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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,690	03/15/2002	John H. Stevens	HRT-293	7079

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EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	17

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,690	STEVENS ET AL.	
	Examiner	Art Unit	
	DAVID J ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *MPEP SECTION 804 PAGE 800-16*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-53 and 69-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll, et al (5309896) in view of either of Edwards, et al (5293869) or Imran (5156151).

Moll, et al discloses a method for retracting an organ inside the body in the course of treating adjacent tissue. Moll, et al teaches a procedure in which a small, oblate version of a Type I or Type II retraction device is used to displace the pericardium 403 from the heart 408 is shown in FIG. 15, which shows a transverse cross section of the chest. Displacement of the pericardium allows the outer surface 413 of the heart 408 to be observed, and such procedures as endocardial mapping, ablation, transmyocardial revascularization, and defibrillation to be carried out. These procedures have until now been difficult to do laparoscopically because access to the surface of the heart 408 is obstructed by the pericardium 403. Moll,et al is not specific to the particulars concerning the actual ablating procedures. Imran and Edwards, et al disclose ablation and mapping devices that maybe used during a beating heart procedure thereby obviating the need for the complication of a by-pass setup. To use a device/method similar to that as taught by either of Imran and Edwards in combination with the retraction method of Moll, et al

would have been obvious to one with ordinary skill in the art in order to avoid more costly surgical intervention and trauma. The combination of the references would yield a method for forming a lesion in heart tissue of a patient including providing an ablating device, creating an opening in the patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity; pass the electrode through the opening; positioning the electrode adjacent the heart tissue and ablating the heart tissue while the heart is beating.

Claim 39, the creation of a second opening for accessing the interior volume of the heart is met by the disclosure of either of Edwards or Imran.

Claim 40, the use of a trocar for accessing the tissue site is disclosed by Moll, et al.

Claims 41,42,43,44, Moll, et al recognizes the placement of the opening intercostally. See figure 16A.

Claim 45 see devices as disclosed by Imran and Edwards.

Claim 47 is similar to claim 38 except that the claim is broader in scope in that it does not require the use of an electrode. The rejection to claim 38 is equally applicable to claim 47.

Claims 48-53 are similar in scope to claims 39-45 supra and the rejections to claims 39-45 are equally applicable to claims 48-55.

Claims 69 and 70 are similar to claim 38 except that the claim is broader in scope in that it does not require the step of ablating. The rejection to claim 38 is equally applicable to claims 69 and 70.

Claims 71-73 are similar in scope to 42-44 claims supra and the rejections to claims 42-44 are equally applicable to claims71-73.

Claims 54-56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moll, et al as modified by the secondary references and as applied to claim 47 above, and further in view of Desai (4940064)

Imran and Edwards,et al teach ablation devices having electrodes whereas Desai teaches ablation devices using either radiofrequency or laser as the energy source for ablating the tissues. To use either radiofrequency or laser in place of electrode for ablating tissues would have been obvious to one with ordinary skill in the art based on the doctrine of equivalent elements. It is clear that one form of energy may be substituted for another form based on surgical consideration without departing from the scope of the surgical method of ablating targeted heart tissues.

Claims 57-68 rejected under 35 U.S.C. 103(a) as being unpatentable over Moll,et al in view of Imran or Edwards, et al as applied to claim47 above, and further in view of Lundquist (19940621).

Moll,et al is not specific to the particulars concerning the actual ablating procedures and Lundquist is yet another known type of electrode ablating device having a flexible tip that is capable of creating a compressive force. It is clear that one typeof electrode ablating device may be substituted for another based on surgical

considerations without departing from the scope of the surgical method of ablating targeted heart tissues.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-53 and 69-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6161543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Cox, et al'543 is directed to a method of forming a lesion in the heart tissue including the steps of providing at least one ablation device, introducing the ablation device into the patient's chest, positioning the ablation device in contact with an epicardial surface of the heart, ablating the heart tissue to create a lesion. The specification, column 3, utilizes the method on a beating heart. Clearly at the time of the invention, it was known to use this technique on a beating heart as disclosed by Cox, et al.

Claim 39, the use of a second opening at the time of the invention was known as disclosed in column 13 by Cox, et al.

Claim 40, see column 13 of Cox, et al.

Claims 41-44, see claim 7.

Claims 45, see column 8 of Cox, et al.

Claims 46-53 and 69-73 are similar in scope to the preceding claims and the rejections to these claims are equally applicable.

With respect to the double patenting, see attached copy of the Office guidelines from MPEP 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
MARCH 7, 2004